With this response, claim 1 is now pending. Applicants do not believe that any fees other than a one month extension of time (for which payment is provided for in the accompanying Petition) are due at this time; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to this document, the Commissioner is authorized to deduct the fees from Deposit Account No. 13-4125 referencing docket number 38-21(15404)B.

I. Rejection under 35 U.S.C. § 101

Claim 1 was rejected under 35 U.S.C. §101, because the claimed invention is allegedly not supported by either specific and/or substantial utility or a well established utility as outlined in the Revised Interim Utility Guidelines Training Materials ("Interim Guidelines"). Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "probes for hybridization assays, primers for amplification methods, marker nucleic acids, the isolation of full-length cDNAs or genes,...used to make protein and ...to make the corresponding antibodies, isolation of homologous sequences, detection of gene expression, and for numerous other generic genetic engineering usages." Office Action at page 5. The Examiner further recognizes that "protein may be used for detection of expression, antibody production, Western blots, etc." Office Action at page 5. However, the examiner contends that none of these utilities constitutes a "substantial" or "specific" utility as defined in the "Interim Guidelines."

Applicants respectfully disagree. The application of the "Interim Guidelines" ignores the presently disclosed utilities and contravenes well-established doctrines of utility developed in the courts.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes multiple objectives and utilities that are met by the present invention. For example, the claimed nucleic acid molecules are useful in determining the presence of polymorphisms, isolating specific promoter sequences, and isolating a variety of agronomically significant genes, including but not limited to identifying genes that are necessary for the interception and transformation of light energy via photosynthesis, genes that are instrumental in preventing lodging or control of plant height; genes that modify vascular structure for support, genes that regulate meiosis, cell division, carotenoids, floral biogenesis, *etc.* (*see e.g.,* Specification, beginning at page 31, under heading "Uses and Agents of the Invention").

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. §101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.,* the claimed nucleic acid molecules may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is

indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. §101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather, the Examiner attempts to undermine the existing utilities by stating that the "...disclosed uses of these compositions are not specific and are generally applicable to any nucleic acid." Office Action at page 5. The Examiner further contends that, "[t]hese are non-specific uses that are applicable to nucleic acid(s) and/or proteins in general and not particular or specific to the nucleic acids being claimed." Office Action at page 5.

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC,* 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty,* 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the

case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. §101.

Surprisingly, the Examiner states that the credibility of the presently asserted utilities has not been assessed. Office Action at page 6. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the

credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...").

Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claim 1 under 35 U.S.C. §101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

II. Rejection under 35 U.S.C. §112, 1st Paragraph: Enablement

Claim 1 was rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.* an invention with no utility cannot be enabled). Applicants respectfully traverse this rejection, and note that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

III. Rejection of Claim 1 under 35 U.S.C. §112, 1st Paragraph: Written Description

Claim 1 was also rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking an adequate written description. Applicants respectfully traverse this rejection.

The Examiner admits that "SEQ ID NOs: 1 - 10 *per se* meet the written description and enablement provisions of 35 U.S.C. §112, first paragraph." Office Action at page 7. However, the Examiner rejects claim 1 as "directed to encompass gene sequences, corresponding sequences from other species with corresponding encoding fragments, mutated sequences, allelic variants, splice variants, sequences that have a degree of identity (similarity, homology), and so forth." Office Action at page 7. According to the Examiner, the specification provides insufficient written description to support the genus encompassed by the claims. However, such an assertion is unfounded.

As the Examiner notes, the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247,

1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader that the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-Mar-Co.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, simply because the claimed nucleic acid sequences may also include mutations, allelic variations, splice variations and the like, does not require that Applicants describe each and every one of these molecules.

The Examiner further contends that the skilled artisan cannot envision the detailed chemical structure of the claimed polynucleotides. According to the Examiner, proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every sequence encompassed by that claim. In support of this proposition, the Examiner relies on *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). Applicants respectfully disagree.

Applicants assert that the genus of sequences encompassed by the presently amended claim are supported by Applicants' disclosure of common structural attributes. Specifically, Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NOs: 1 – 10. Moreover, closely related nucleic acid molecules falling within the scope of the present claim are readily recognizable – they either hybridize under the presently claimed conditions to SEQ ID NOs: 1 – 10, or they do not. The fact that the nucleic acid molecules may comprise additional sequences, or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the present specification.

Consequently, the present case is clearly different from *Eli Lilly*. The present claims "distinguish the claimed invention from others" and define "structural features commonly possessed by members of the genus that distinguishes them from others," unlike the claims at issue in *Eli Lilly*. 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997) ("a cDNA is not defined or described by the mere name 'cDNA'...but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA."). Thus, there is no deficiency in the written description support for the claimed invention.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

IV. Rejection under 35 U.S.C. §102

Claim 1 was rejected under 35 U.S.C. §102(b) as allegedly being anticipated by the Sigma Chemical Catalog. The Examiner contends that various oligonucleotides such as dimers and trimers of A or T bases, cited in the catalog, are also "fragments of each instantly claimed SEQ ID NOs 1 – 10 as are included in instant claim 1." Applicants respectfully traverse this rejection.

Applicants disagree. Whatever else the Catalog teaches, it does not teach nucleic acid sequences selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 10. Nevertheless, to facilitate prosecution Applicants have amended claim 1 to remove the phrase "fragments thereof". Applicants submit that the Catalog does not anticipate the presently claimed invention, and request that the rejection of claim 1 under 35 U.S.C. §102(b) be withdrawn.

V. Objection to the Disclosure

The Examiner objects to the disclosure because it contains an embedded hyperlink and/or other forms of browser-executable code on page 5, lines 18 and 20 of the specification. According to MPEP §608.01, embedded hyperlinks and browser executable code are not permitted. The specification has been amended to remove the phrase "http://."

In view of the above, the presently pending claim is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned with respect to any unresolved issues remaining in this application.

Respectfully submitted,

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Marked-Up Versions of Amended Specification & Claims

At page 5 of the specification:

Similarity analysis includes database search and alignment. Examples of public databases include the DNA Database of Japan (DDBJ) (**[http://]**www.ddbj.nig.ac.jp/); Gen**[e]**Bank (**[http://]**www.ncbi.nlm.nih.gov/web/GenBank/Index.html); and the European Molecular Biology Laboratory Nucleic Acid Sequence Database (EMBL) (**[http://]**www.ebi.ac.uk/ebi_docs/embl_db.html). A number of different search algorithms have been developed, one example of which are the suite of programs referred to as BLAST programs. There are five implementations of BLAST, three designed for nucleotide sequence queries (BLASTN, BLASTX, and TBLASTX) and two designed for protein sequence queries (BLASTP and TBLASTN) (Coulsen, *Trends in Biotechnology*, 12: 76-80 (1994); Birren, *et al., Genome Analysis*, 1: 543-559 (1997)).

In the claims:

1. (Amended) A substantially purified nucleic acid molecule that encodes a *Arabidopis thaliana* protein **[or fragment thereof]** comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: **10** **[1425]**.